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November 10,1998

834/19/19

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Promotes a Healthy Prostate

Clinical research indicates that regular use of saw palmetto provides phytonutrients that may help maintain a healthy prostate.

on the following product:

Tree of Life® Saw Palmetto

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs

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